

## § 177.1430

## 21 CFR Ch. I (4–1–09 Edition)

in the production of the polymers. The optional adjuvant substances required in the production of the polymers may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and aluminum chloride.

(c) The provisions of this section are not applicable to polyisobutylene used in food-packaging adhesives complying with § 175.105 of this chapter.

### § 177.1430 Isobutylene-butene copolymers.

Isobutylene-butene copolymers identified in paragraph (a) of this section may be safely used as components of

articles intended for use in contact with food, subject to the provisions of this section.

(a) For the purpose of this section, isobutylene-butene copolymers consist of basic copolymers produced by the copolymerization of isobutylene with mixtures of *n*-butenes such that the finished basic copolymers contain not less than 45 weight percent of polymer units derived from isobutylene and meet the specifications prescribed in paragraph (b) of this section when tested by the methods described in paragraph (c) of this section.

(b) *Specifications:*

| Isobutylene-butene copolymers  | Molecular weight (range) | Viscosity (range)                           | Maximum bromine value |
|--|--------------------------|---|-----------------------|
| 1. Used as release agents in petroleum wax complying with § 178.3710 of this chapter.  | 300 to 5,000 ...         | 40 to 20,000 seconds Saybolt at 200 °F.     | 40                    |
| 2. Used as plasticizers in polyethylene or polypropylene complying with § 177.1520, and in polystyrene complying with § 177.1640.  | 300 to 5,000 ...         | 40 to 20,000 seconds Saybolt at 200 °F.     | 40                    |
| 3. Used as components of nonfood articles complying with §§ 175.300, 176.170, 176.210, 177.2260(d)(2), 177.2800, and 178.3570 (provided that addition to food does not exceed 10 parts per million), or § 176.180 of this chapter. | 300 to 5,000 ...         | 40 to 20,000 seconds Saybolt at 200 °F.     | 40                    |
| 4. Used as production aids in the manufacture of expanded (foamed) polystyrene articles complying with § 177.1640 of this chapter.   | 150 to 5,000 ...         | Less than 20,000 seconds Saybolt at 200 °F. | 90.                   |
| 5. Used in release coatings on backings or linings for pressure-sensitive adhesive labels complying with § 175.125 of this chapter.  | 150 to 5,000 ...         | Less than 20,000 seconds Saybolt at 200 °F. | 90                    |

(c) The analytical methods for determining whether isobutylene-butene copolymers conform to the specifications in paragraph (b) are as follows:

(1) *Molecular weight.* Molecular weight shall be determined by American Society for Testing and Materials (ASTM) method D2503–82, “Standard Test Method for Molecular Weight (Relative Molecular Mass) of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(2) *Viscosity.* Viscosity shall be determined by ASTM method D445–74, “Test

for Kinematic Viscosity of Transparent and Opaque Liquids,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(3) *Maximum bromine value.* Maximum bromine value shall be determined by ASTM method D1492–78, “Standard Test Method for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(d) The provisions of this section are not applicable to isobutylene-butene copolymers used as provided under § 175.105 of this chapter.

[52 FR 11641, Apr. 10, 1987, as amended at 63 FR 36175, July 2, 1998]